

## PART III: CONSUMER INFORMATION

### Pr LUPRON<sup>®</sup> leuprolide acetate injection

This leaflet is part III of a three-part "Product Monograph" published when LUPRON<sup>®</sup> Injection was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about LUPRON<sup>®</sup> Injection. Contact your doctor or pharmacist if you have any questions about the drug.

#### ABOUT THIS MEDICATION

##### What the medication is used for:

LUPRON<sup>®</sup> (leuprolide acetate) Injection is used in the palliative treatment of prostate cancer. Palliative treatment is the relief of symptoms associated with a disease; it is not a cure.

##### What it does:

Leuprolide acetate is chemically similar to gonadotropin releasing hormone (GnRH or LH-RH) a hormone which occurs naturally in your body. Normally, your body releases small amounts of LH-RH and this leads to events which stimulate the production of sex hormones. However when you inject LUPRON<sup>®</sup> Injection, the normal events that lead to sex hormone production are interrupted and testosterone is no longer produced by the testes. Decreasing the levels of testosterone leads to decreased symptoms associated with prostate cancer.

##### When it should not be used:

LUPRON<sup>®</sup> Injection should not be used:

- If you are allergic to leuprolide acetate, any similar nonapeptides (e.g., histrelin, desorelin), or any of the nonmedicinal ingredients in LUPRON<sup>®</sup> Injection.
- In women who are or may become pregnant.
- In women who are breast-feeding.

##### What the medicinal ingredient is:

Leuprolide acetate

##### What the important nonmedicinal ingredients are:

Each 2.8 mL multiple-dose vial contains sodium chloride, **benzyl alcohol**, sterile water for injection, sodium hydroxide and/or acetic acid.

##### What dosage forms it comes in:

LUPRON<sup>®</sup> Injection is a drug which contains 5 mg of leuprolide acetate per mL. It comes in 2.8 mL multiple-dose vials. LUPRON<sup>®</sup> Injection is supplied as a 14-day kit.

#### WARNINGS AND PRECAUTIONS

**BEFORE you use LUPRON<sup>®</sup> Injection talk to your doctor or pharmacist if:**

- You are allergic to any component of the medication
- You have previous history of obstructive uropathy (difficulty urinating due to a block in the urinary tract)
- You have family history of osteoporosis or are a chronic user of drugs that can reduce bone mass such as anticonvulsants, corticosteroids, alcohol and/or tobacco. LUPRON<sup>®</sup> Injection can cause thinning of the bone and may pose additional risk in patients with such a history.

During the first few weeks of treatment with LUPRON<sup>®</sup> Injection, you may experience worsening of symptoms or onset of new symptoms, including bone pain, presence of blood in the urine, or difficulty urinating.

#### INTERACTIONS WITH THIS MEDICATION

Tell your doctor and pharmacist if you are taking, have been taking, or planning to take any other medicines, including non-prescription drugs (such as drug products for colds or nausea).

#### PROPER USE OF THIS MEDICATION

##### Usual dose:

The recommended dose of LUPRON<sup>®</sup> Injection is 1 mg (0.2 mL), as a single daily subcutaneous injection

Only a small amount of LUPRON<sup>®</sup> Injection is needed once a day. Use the recommended ½ cc presterilized disposable syringe (see Instructions for Use Leaflet). Syringes are provided in the Patient Administration Kit.

Change the site of injection as instructed by your doctor.

As a guide, the usual sites of injection are indicated below:

##### SUGGESTED ROTATION OF THE INJECTION SITE



##### Missed Dose:

Follow these instructions unless instructed otherwise by your doctor: if you miss an injection at the usual time, take it as soon as you remember, if you remember on the same day. If not, do not take the missed dose at all. Simply wait until it is time for your next dose. Do not take two doses at once.

Do not stop your daily injections because you feel better. You need one injection a day to make sure LUPRON<sup>®</sup> Injection keeps working for you.

It is very important that your doctor check your progress at regular medical visits.

*This is not a complete list of side effects. For any unexpected effects while taking LUPRON® Injection, contact your doctor or pharmacist.*

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

In the first few weeks of taking LUPRON® Injection, your testosterone levels will initially increase and then decline over several weeks. During this period some patients may experience worsening of urinary symptoms and/or a temporary increase in bone pain. **Should this occur, contact your doctor immediately.**

The following side effects are commonly experienced after the initial rise and occur due to decreasing levels of testosterone in the body:

- general pain or flu-like symptoms
- hot flashes / sweats
- joint and muscle pain
- emotional changes such as feeling depressed
- worsening urinary symptoms

Should these side effects persist or if they are severe, contact your doctor immediately.

A local skin reaction may occur: itching, redness, burning, and/or swelling at the injection site. These reactions usually are mild and disappear after a few days. If they persist or worsen, tell your doctor.

**HOW TO STORE IT**

Store LUPRON® Injection vials or kits in the refrigerator (2°C to 8°C) and protect from light (keep in carton until use).

As with other medications, KEEP OUT OF REACH OF CHILDREN.

**REPORTING SUSPECTED SIDE EFFECTS**

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345  
 toll-free fax 866-678-6789  
 By email: [cadrm@hc-sc.gc.ca](mailto:cadrm@hc-sc.gc.ca)

By regular mail:  
 National AR Centre  
 Marketed Health Products Safety and Effectiveness  
 Information Division  
 Marketed Health Products Directorate  
 Tunney's Pasture, AL 0701C  
 Ottawa ON K1A 0K9

*NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.*

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	Abnormal swelling or numbness of limbs		✓	
	Severe bone pain		✓	
	Severe pain in chest or abdomen		✓	
	Vision Changes		✓	
Common	Decrease in testicular size		✓	
	Difficulty urinating		✓	
	Headache	✓		
	Hot flashes		✓	
	Impotence/ decrease in libido		✓	
	Itching Rash		✓	
	Skin reactions including reaction at site of injection		✓	
Vomiting / nausea	✓			

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.abbott.ca> or by contacting the sponsor, Abbott Laboratories, Limited at: 1-800-361-7852.

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